



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,554	10/06/2000	John F. Engelhardt	875.024US1	4157

21186 7590 12/04/2001

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. BOX 2938  
MINNEAPOLIS, MN 55402

EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
----------	--------------

1648

DATE MAILED: 12/04/2001

6

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/684,554

Applicant(s)

ENGELHARDT ET AL.

Examiner

Ulrike Winkler, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_                      6) ☐ Other: \_\_\_\_\_

Art Unit: 1648

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group	Claim #	Description
1	1-7, 9 and 24, 25	Drawn to a composition comprising at least two recombinant AAV sequences, the first AAV sequence comprises three DNA segments, the first and third DNA segments are made up of the 5' and 3' AAV LTR respectively, the second DNA segment does not contain AAV DNA. The second segment of the first AAV sequence comprises a portion of ORF and a <b>promoter</b> . The second AAV sequence comprising the remainder of the ORF so that the combination (first and second AAV sequences) encodes a full-length polypeptide, classified in class 435, subclass 320.1.
2	8	The second segment of the first AAV sequence comprises a portion of the ORF and an <b>enhancer</b> , classified in class 536, subclass 24.1.
3	10	The second AAV sequence comprises a second DNA segment which comprises a portion of the ORF and an <b>enhancer</b> , classified in class 536, subclass 24.1.
4	11	The second AAV sequence comprises a second DNA segment which comprises a portion of the ORF and a <b>promoter</b> , classified in class 536, subclass 24.1.
5	12-15	The second segment of the first AAV sequence comprises a an origin of replication and a nucleotide encoding a protein that binds to the origin of replication, classified in class 435, subclass 320.1.
6	16, 17	The second AAV sequence comprises a second DNA segment which comprises a portion of the ORF and a <b>promoter</b> , classified in class 930, subclass 6.
7	18, 22, 23 44, 45	A recombinant adeno-associated viral vector comprising a heterologous origin of replication, classified in class 435, subclass 320.1.
8	19, 20, 23	A recombinant adeno-associated viral vector comprising heterologous transcriptional elements functional in a host cell, wherein the element is a <b>promoter</b> , classified in class 435, subclass 320.1.
9	19, 21, 23	A recombinant adeno-associated viral vector comprising heterologous transcriptional elements functional in a host cell, wherein the element is an <b>enhancer</b> , classified in class 435, subclass 320.1.
10	<del>25</del> -31, 33 26	Drawn to a method of gene transfer using a composition comprising at least two recombinant AAV sequences, the first AAV sequence comprises three DNA segments, the first and third DNA segments are made up of the 5' and 3' AAV LTR respectively, the second DNA segment does not contain AAV DNA. The second segment of the first AAV sequence comprises a portion of ORF and a <b>promoter</b> . The second AAV sequence comprises segment comprises a portion of ORF so that the combination encodes a full-length polypeptide, classified in class 930, subclass 33.

Art Unit: 1648

11	32	The method were the second segment of the first AAV sequence comprises a portion of ORF and an <b>enhancer</b> , classified in class 930, subclass 33.
12	34, 36	The method were the second AAV sequence comprises a second DNA segment which comprises a portion of ORF and an <b>enhancer</b> , classified in class 930, subclass 33.
13	35, 37	The method were the second AAV sequence comprises a second DNA segment which comprises a portion of ORF and a <b>promoter</b> , classified in class 930, subclass 33..
14	38-41	The method were the second segment of the <b>first AAV sequence</b> comprises an origin of replication and a nucleotide encoding a protein that <b>binds to the origin of replication</b> , classified in class 930, subclass 33.
15	42, 43	The method were the second segment of the <b>second AAV sequence</b> comprises a an origin of replication and a nucleotide encoding a protein that <b>binds to the origin of replication</b> and comprising a promoter, classified in class 930, subclass 6..

The inventions are distinct, each from the other because of the following reasons:

Groups 1-9 are compositions and are distinct from groups 10-15 which are drawn to methods. Groups 1-9 are compositions and each is distinct from the other because they contain different materials. Groups 1-9 comprises DNA sequences encoding vectors, each vector comprises different sequences an therefore they would not be structurally the same. Though there may be overlap for these groups, because of their structural differences the search for one group will not be coextensive with that of the other group.

Groups 10-15 are drawn to methods and each is distinct from the other because they utilize different starting materials, therefore the outcomes are not be expected to be the same. The combination of the vectors used in the method steps are different hence the outcomes would not be expected to be the same. The search for each combination of vectors in the methods steps would require a different search of the art.

Art Unit: 1648

Inventions of groups 1-4 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not rely solely upon either subcombination as claimed for its own patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not rely solely upon either subcombination for its own patentability as claimed because the subcombination has separate utility in that each AAV vector can be separately used as an expression tool for the production of proteins which can be used in turn as an immunogen, as such each subcombination will produce a different protein which will produce a different antibody profile.

If the office determines that the elected subcombination or combination of subcombinations to be allowable, then claims requiring that subcombination or combination of subcombinations with respect to the elected invention 1-4 will be rejoined for examination.

Inventions groups 10-13 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not rely solely upon either subcombination as claimed for its own patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not rely solely upon either subcombination for its own patentability as claimed because the subcombination has separate utility in that each AAV vector can be separately used as an expression tool for the production of proteins which can be used in turn as an immunogen, as such each subcombination will produce a different protein which will produce a different antibody profile.

Art Unit: 1648

If the office determines that the elected subcombination or combination of subcombinations to be allowable, then claims requiring that subcombination or combination of subcombinations with respect to the elected invention 10-13 will be rejoined for examination.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent subject matter and different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

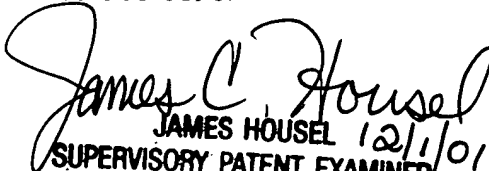
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Ulrike Winkler, Ph.D.

  
JAMES HOUSEL 12/1/01  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600